

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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MALLINCKRODT PLC, MALLINCKRODT  
PHARMACEUTICALS  
IRELAND LIMITED, MALLINCKRODT  
HOSPITAL PRODUCTS IP UNLIMITED  
COMPANY, and INO THERAPEUTICS LLC,

C.A. No. 22-01648 (RGA)

**JURY TRIAL DEMANDED**

Plaintiffs,

v.

AIRGAS THERAPEUTICS LLC, AIRGAS  
USA LLC, and AIR LIQUIDE S.A.,

Defendants.

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**ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF  
AIRGAS THERAPEUTICS LLC AND AIRGAS USA LLC TO FIRST AMENDED  
COMPLAINT**

Defendants Airgas Therapeutics LLC (“Airgas Therapeutics”) and Airgas USA LLC (“Airgas USA”) (collectively “Airgas”), hereby respond to Plaintiffs Mallinckrodt PLC, Mallinckrodt Pharmaceuticals Ireland Limited (“Mallinckrodt Ireland”), Mallinckrodt Hospital Products IP Unlimited Company (“Mallinckrodt Hospital”) and INO Therapeutics LLC (INO Therapeutics), (collectively, “Plaintiffs”) First Amended Complaint and present their affirmative defenses and counterclaims, as follows:

**NATURE OF THE ACTION**

1. Paragraph 1 contains conclusions of law to which no response is required. To the extent a response is required, Airgas admits that the Complaint purports to state an action for patent infringement under the patent laws of the United States, pursuant to title 35 of the United States Code. Airgas admits that Airgas Therapeutics has applied for approval of Abbreviated

New Drug Application (“ANDA”) No. 203144 (“Airgas’s ANDA”), seeking approval of a generic version of INOmax®, 800 ppm (“Airgas’s ANDA Product”). Airgas admits that according to the information provided by the FDA on its website, United States Patent Nos. 8,795,741 (“the ’741 patent”), 8,776,794 (“the ’6,794 patent”), 8,776,795 (“the ’795 patent”), and 9,279,794 (“the ’9,794 patent”) are listed in the FDA’s Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) in connection with INOmax®, 800 ppm (collectively, the “Orange Book Patents”), and that U.S. Patent Nos. 10,773,046 (“the ’046 patent”) and 9,919,118 (“the ’118 patent”) are not listed in the Orange Book (collectively all patents, the “Patents-In-Suit”). Except as otherwise expressly admitted, Airgas lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs’ remaining allegations and therefore denies them.

### **THE PARTIES**

2. Airgas lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 and therefore denies the same.

3. Denied.

4. Upon information and belief, Airgas admits that according to the information provided by the FDA on its website, Mallinckrodt Hospital is listed as the holder of NDA No. 020845 for INOmax®, 800 ppm. Except as otherwise expressly admitted, Airgas lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs’ remaining allegations and therefore denies them.

5. Airgas lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 5 and therefore denies the same.

6. Admitted.

7. Airgas admits that Airgas Therapeutics develops, manufactures, markets, and sells medical gases and equipment. Airgas denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

8. Airgas states that the website speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph. Allegations not expressly admitted are denied.

9. Airgas admits that Airgas USA is a limited liability corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 259 N. Radnor Chester Road, Suite 100, Radnor, PA 19087. Airgas denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

10. Airgas admits that Airgas USA is a supplier of industrial, medical, and specialty gases. Airgas denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

11. Airgas states that the website speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph. Allegations not expressly admitted are denied.

12. Paragraph 12 contains allegations regarding Air Liquide S.A. As such, no response is required from Airgas.

13. Paragraph 13 contains allegations regarding Air Liquide S.A. As such, no response is required from Airgas.

14. Denied.

15. Airgas admits that Airgas Therapeutics develops, manufactures, markets, and sells medical gases and equipment. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

16. Airgas admits that Airgas USA is a supplier of industrial, medical, and specialty gases. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

17. Airgas lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17 and therefore denies the same.

18. Airgas admits that Airgas Therapeutics submitted ANDA No. 203144 to FDA for approval of the product described therein prior to the expiration of the Orange Book Patents. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

19. The allegations in this paragraph are speculative in nature, and Airgas denies them on that basis. Allegations not expressly admitted are denied.

#### **JURISDICTION AND VENUE**

20. Paragraph 20 contains conclusions of law for which no response is required. To the extent that a response is required, and solely for the limited purposes of this action, Airgas does not contest subject matter jurisdiction as to Plaintiffs' infringement allegations against Airgas Therapeutics or Airgas USA.

21. Solely for the purpose of this litigation, Airgas does not contest personal jurisdiction over Airgas Therapeutics or Airgas USA. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

22. Airgas admits that Airgas Therapeutics has applied for approval of ANDA No. 203144. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

23. Denied.

24. Denied.

25. Paragraph 25 contains conclusions of law to which no response is required. To the extent a response is required, and solely for the limited purposes of this action, Airgas does not contest personal jurisdiction in the District of Delaware in this matter. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

26. Paragraph 26 contains conclusions of law to which no response is required. To the extent a response is required, and solely for the limited purposes of this action, Airgas does not contest personal jurisdiction in the District of Delaware in this matter. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

27. Paragraph 27 contains conclusions of law to which no response is required. To the extent a response is required, and solely for the limited purposes of this action, Airgas does not contest personal jurisdiction in the District of Delaware in this matter. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

28. Paragraph 28 contains conclusions of law to which no response is required. To the extent a response is required, and solely for the limited purposes of this action, Airgas does not contest personal jurisdiction in the District of Delaware in this matter. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

29. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Airgas lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the same.

30. Paragraph 30 contains conclusions of law to which no response is required. To the extent a response is required, and solely for the limited purposes of this action, Airgas does not contest venue in the District of Delaware in this matter. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

31. Paragraph 31 contains conclusions of law to which no response is required. To the extent a response is required, and solely for the limited purposes of this action, Airgas lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29, and therefore denies the same.

32. Denied.

#### **INOMAX® AND BACKGROUND OF THE INVENTIONS**

33. Upon information and belief, Airgas admits that according to information provided by the FDA on its website: Mallinckrodt Hospital Products IP Limited is listed as the holder and U.S. Agent for NDA No. 020845 for INOMAX® (Nitric Oxide) inhalation gas, 100 ppm and 800 ppm and that FDA approved NDA No. 020845 in December 1999 for administration by inhalation to neonates and children suffering from hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. Upon information and belief, Airgas admits that Mallinckrodt's nitric oxide 800 ppm for inhalation product is sold in the United States under the trademark INOmax®. Airgas lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, on that basis, denies them.

34. Paragraph 34 contains conclusions of law to which no response is required. To the extent a response is required, Airgas admits that according to the information provided by the FDA on its website, the following 15 patents are listed in the Orange Book for INOmax<sup>®</sup> (nitric oxide gas 800 ppm): the '570 patent, the '966 patent, the '284 patent, the '163 patent, the '741 patent, the '904 patent, the '209 patent, the '210 patent, the '6,794 patent, the '795 patent, the '911 patent, the '9,794 patent, the '802 patent, the '993 patent, and the '112 patent. Except as otherwise expressly admitted, Airgas lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' remaining allegations and therefore denies them.

35. Paragraph 35 contains conclusions of law to which no response is required. To the extent a response is required, Airgas lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

36. Paragraph 36 contains conclusions of law to which no response is required. To the extent a response is required, Airgas lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them.

37. Upon information and belief, Airgas admits that Mallinckrodt previously asserted the '966, '284, '741, '163, '112, '6,794, '795, '209, '911, '802, and '9,794 patents in *Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distribution, Inc.*, 1:15-cv-00170 (D. Del.) ("the Praxair Litigation"), alleging infringement under 35 U.S.C. §§ 271(e)(2) and 271(a), (b) and/or (c). The district court decision referred to the '966, '284, '741, '163, and '112 patents as the "HF patents" and held that all of the asserted claims of the HF patents were invalid under 35 U.S.C. § 101. *See* D.E. 308. The district court decision referred to the '6,794, '795, '209, '911, and '802 patents as the "DSIR patents" and held that the asserted claims of the DSIR patents were not infringed. *See* D.E. 308. The district court decision referred to the '9,794 patent as the "Sensor

Drift Patent” and held that the asserted claims of the Sensor Drift Patent were not infringed. *See* D.E. 308. The district court found that each of the patent claims ultimately asserted by Mallinckrodt against Praxair was either invalid or not infringed. The Federal Circuit upheld the district court’s invalidity and non-infringement findings concerning the asserted claims. *See INO Therapeutics LLC v. Praxair Distribution Inc.*, 782 Fed. Appx. 1001 (Fed. Cir. 2019).

38. Paragraph 38 contains conclusions of law to which no response is required. To the extent a response is required, denied.

### **THE PATENTS-IN-SUIT**

39. Upon information and belief, Airgas admits that the USPTO issued the ’741 patent, titled “Methods for treating patients who are candidates for inhaled nitric oxide treatment” on August 5, 2014 and that a purported copy of the ’741 patent is attached to the Complaint as Exhibit 2. Airgas denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

40. Denied.

41. Airgas admits that the FDA Orange Book lists the ’741 patent in connection with NDA No. 020845 for INOmax®, 800 ppm.

42. Airgas states that the ’741 patent speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

43. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, denied.

44. Upon information and belief, Airgas admits that the USPTO issued the ’6,794 patent, titled “Nitric oxide delivery device,” on July 15, 2014 and that a purported copy of the



'6,794 patent is attached to the Complaint as Exhibit 3. Airgas denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

45. Denied.

46. Airgas admits that the FDA Orange Book lists the '6,794 patent in connection with NDA No. 020845 for INOmax®, 800 ppm.

47. Airgas states that the '6,794 patent speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

48. Upon information and belief, Airgas admits that the USPTO issued the '795 patent, titled "Gas delivery device and system," on July 15, 2014 and that a purported copy of the '795 patent is attached to the Complaint as Exhibit 4. Airgas denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

49. Denied.

50. Airgas admits that the FDA Orange Book lists the '795 patent in connection with NDA No. 020845 for INOmax®, 800 ppm.

51. Airgas states that the '795 patent speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

52. Upon information and belief, Airgas admits that the USPTO issued the '9,794 patent, titled "Systems and methods for compensating long term sensitivity drift of electrochemical gas sensors exposed to nitric oxide," on March 8, 2016 and that a purported copy of the '9,794 patent is attached to the Complaint as Exhibit 5. Airgas denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

53. Denied.

54. Airgas admits that the FDA Orange Book lists the '9,794 patent in connection with NDA No. 020845 for INOmax®, 800 ppm.

55. Airgas states that the '9,794 patent speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

56. Upon information and belief, Airgas admits that the USPTO issued the '046 patent, titled "Apparatus and method for monitoring nitric oxide delivery," on September 15, 2020, and that a purported copy of the '046 patent is attached to the Complaint as Exhibit 6. Airgas denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

57. Denied.

58. Airgas states that the '046 patent speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

59. Upon information and belief, Airgas admits that the USPTO issued the '118 patent, titled "Systems and methods for compensating long term sensitivity drift of electrochemical gas sensors exposed to nitric oxide," on March 20, 2018 and that a purported copy of the '118 patent is attached to the Complaint as Exhibit 7. Airgas denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

60. Denied.

61. Airgas states that the '118 patent speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

#### **DEFENDANTS' ACTS OF INFRINGEMENT**

62. Airgas admits that Airgas Therapeutics submitted ANDA No. 203144 to FDA for approval of the product described therein prior to the expiration of the '966 patent, '904 patent,

‘284 patent, ‘163 patent, ‘209 patent, ‘210 patent, ‘794 patent, ‘795 patent, ‘741 patent, ‘112 patent, ‘911 patent, ‘9,794 patent, ‘802 patent, ‘993 patent, and the ‘570 patent. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

63. Denied.

64. Airgas admits that Airgas Therapeutics submitted 510(k) No. K212409 to FDA for approval of the device described therein. All remaining allegations in this paragraph of the Complaint are speculative in nature and are denied. Allegations not expressly admitted are denied.

65. Airgas states that Airgas’s ANDA and its regulatory record speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

66. Airgas states that Airgas Therapeutics’ Notice Letter speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

67. Airgas states that Airgas’s ANDA speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

68. Airgas states that Airgas’s ANDA speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

69. Airgas states that Airgas’s ANDA speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

70. Airgas states that Airgas’s ANDA and its regulatory record speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

71. Airgas states that Airgas's ANDA and its regulatory record speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

72. Airgas avers that Plaintiffs filed this action in bad faith. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

73. Airgas states that Airgas Therapeutics' Notice Letter speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph.

74. Denied.

75. Denied.

76. Airgas admits that FDA approved Defendants' ANDA on July 27, 2023.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

87. Denied.

88. Denied.

- 89. Denied.
- 90. Denied.
- 91. Denied.
- 92. Denied.
- 93. Denied.
- 94. Denied.
- 95. Denied.
- 96. Denied.
- 97. Denied.
- 98. Denied.
- 99. Denied.
- 100. Denied.
- 101. Denied.
- 102. Denied.
- 103. Denied.
- 104. Denied.
- 105. Denied.
- 106. Denied.
- 107. Denied.
- 108. Denied.
- 109. Denied.
- 110. Denied.
- 111. Denied.

112. Denied.

113. Denied.

114. Denied.

115. Admitted.

116. Admitted.

117. Admitted that Exhibit 8 speaks for itself. Except as otherwise expressly admitted, Airgas denies the remaining allegations in this paragraph. Allegations not expressly admitted are denied.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

123. Denied.

124. Denied.

125. Denied.

126. Denied.

127. Denied.

128. Denied.

129. Denied.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Denied.

136. Denied.

137. Airgas admits that Plaintiffs filed this action on December 30, 2022. Except as otherwise expressly admitted, Airgas lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

**COUNT I FOR PATENT INFRINGEMENT**

**(Infringement of the '6,794 Patent)**

138. Airgas restates and reincorporates its responses to paragraphs 1-137 as if fully set forth herein.

139. Airgas admits that Air Liquide Healthcare American Corporation submitted ANDA No. 203144 and Airgas Therapeutics submitted 510(k) to FDA for approval of the product and device described therein. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

146. Denied.

147. Denied.

148. Denied.

149. Denied.

150. Denied.

**COUNT II FOR DECLARATORY JUDGMENT**  
**(Declaratory Judgement of Patent Infringement of the '6,794 Patent)**

151. Airgas restates and reincorporates its responses to paragraphs 1-150 as if fully set forth herein.

152. Airgas admits only that Plaintiffs purport to bring one or more claims under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

153. Denied.

154. Denied.

155. Denied.

156. Denied.

157. Denied.

158. Denied.

159. Denied.

160. Denied.

161. Denied.

162. Denied.

**COUNT III FOR PATENT INFRINGEMENT**  
**(Infringement of the '6,795 Patent)**

163. Airgas restates and reincorporates its responses to paragraphs 1-162 as if fully set forth herein.



164. Airgas admits that Airgas Therapeutics submitted ANDA No. 203144 and 510(k) to FDA for approval of the product and device described therein. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

165. Denied.

166. Denied.

167. Denied.

168. Denied.

169. Denied.

170. Denied.

171. Denied.

172. Denied.

173. Denied.

174. Denied.

175. Denied.

**COUNT IV FOR DECLARATORY JUDGMENT**  
**(Declaratory Judgement of Patent Infringement of the '795 Patent)**

176. Airgas restates and reincorporates its responses to paragraphs 1-175 as if fully set forth herein.

177. Airgas admits only that Plaintiffs purport to bring one or more claims under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

178. Denied.

179. Denied.

180. Denied.

181. Denied.

182. Denied.

183. Denied.

184. Denied.

185. Denied.

186. Denied.

187. Denied.

**COUNT V FOR PATENT INFRINGEMENT**  
**(Infringement of the '9,794 Patent)**

188. Airgas restates and reincorporates its responses to paragraphs 1-187 as if fully set forth herein.

189. Airgas admits that Airgas Therapeutics submitted ANDA No. 203144 and 510(k) to FDA for approval of the product and device described therein. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

190. Denied.

191. Denied.

192. Denied.

193. Denied.

194. Denied.

195. Denied.

196. Denied.

197. Denied.

198. Denied.

199. Denied.

200. Denied.

**COUNT VI FOR DECLARATORY JUDGMENT**  
**(Declaratory Judgement of Patent Infringement of the '9,794 Patent)**

201. Airgas restates and reincorporates its responses to paragraphs 1-200 as if fully set forth herein.

202. Airgas admits only that Plaintiffs purport to bring one or more claims under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

203. Denied.

204. Denied.

205. Denied.

206. Denied.

207. Denied.

208. Denied.

209. Denied.

210. Denied.

211. Denied.

212. Denied.

**COUNT VII FOR PATENT INFRINGEMENT**  
**(Infringement of the '741 Patent)**

213. Airgas restates and reincorporates its responses to paragraphs 1-212 as if fully set forth herein.

214. Airgas admits that Airgas Therapeutics submitted ANDA No. 203144 and 510(k) to FDA for approval of the product and device described therein. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

215. Paragraph 215 contains conclusions of law to which no response is required. To the extent a response is required, Airgas admits that the judgment in the Praxair litigation held that all of the asserted claims of the '741 patent, which were claims 1, 4, 7, 9, and 18, are invalid under 35 U.S.C. § 101. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

216. Denied.

217. Denied.

218. Denied.

219. Denied.

220. Denied.

221. Denied.

222. Denied.

223. Denied.

224. Denied.

225. Denied.

226. Denied.

**COUNT VIII FOR DECLARATORY JUDGMENT**  
**(Declaratory Judgement of Patent Infringement of the '741 Patent)**

227. Airgas restates and reincorporates its responses to paragraphs 1-226 as if fully set forth herein.

228. Airgas admits only that Plaintiffs purport to bring one or more claims under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

229. Denied.

230. Denied.

231. Denied.

232. Denied.

233. Denied.

234. Denied.

235. Denied.

236. Denied.

237. Denied.

238. Denied.

**COUNT IX FOR PATENT INFRINGEMENT**  
**(Infringement of the '046 Patent)**

239. Airgas restates and reincorporates its responses to paragraphs 1-238 as if fully set forth herein.

240. Denied.

241. Denied.

242. Denied.

243. Denied.

244. Denied.

245. Denied.

246. Denied.

247. Denied.

248. Denied.

249. Denied.

**COUNT X FOR DECLARATORY JUDGMENT**  
**(Declaratory Judgement of Patent Infringement of the '046 Patent)**

250. Airgas restates and reincorporates its responses to paragraphs 1-249 as if fully set forth herein.

251. Airgas admits only that Plaintiffs purport to bring one or more claims under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

252. Denied.

253. Denied.

254. Denied.

255. Denied.

256. Denied.

257. Denied.

258. Denied.

259. Denied.

260. Denied.

261. Denied.

**COUNT XI FOR PATENT INFRINGEMENT**  
**(Infringement of the '118 Patent)**

262. Airgas restates and reincorporates its responses to paragraphs 1-261 as if fully set forth herein.

263. Denied.

264. Denied.

265. Denied.

266. Denied.

267. Denied.

268. Denied.

269. Denied.

270. Denied.

271. Denied.

272. Denied.

**COUNT XII FOR DECLARATORY JUDGMENT**  
**(Declaratory Judgement of Patent Infringement of the '118 Patent)**

273. Airgas restates and reincorporates its responses to paragraphs 1-272 as if fully set forth herein.

274. Airgas admits only that Plaintiffs purport to bring one or more claims under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Airgas denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

275. Denied.

276. Denied.

277. Denied.

278. Denied.

279. Denied.

280. Denied.

281. Denied.

282. Denied.

283. Denied.

284. Denied.

### **PRAYER FOR RELIEF**

All allegations in Plaintiffs' Complaint not expressly admitted by Airgas are hereby denied. Having answered Plaintiffs' Complaint, Airgas denies Plaintiffs are entitled to any of the relief requested in the Complaint or any relief whatsoever.

### **AFFIRMATIVE DEFENSES**

Without any admission as to burden of proof, burden of persuasion, or the truth of any of the allegations in Plaintiffs' Complaint, Airgas states the following affirmative defenses. Airgas reserves the right to assert additional defenses, as warranted by the facts learned through investigation and discovery.

#### **First Affirmative Defense** **(Failure to State a Claim)**

Plaintiffs fail to state a claim upon which relief can be granted.

#### **Second Affirmative Defense** **(Noninfringement of U.S. Patent No. 8,795,741)**

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Airgas's ANDA No. 203144 and 510(k) No. K212409 infringe or



will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '741 patent.

**Third Affirmative Defense**  
**(Invalidity of U.S. Patent No. 8,795,741)**

Upon information and belief, the claims of the '741 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

**Fourth Affirmative Defense**  
**(Noninfringement of U.S. Patent No. 8,776,794)**

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Airgas's ANDA No. 203144 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '6,794 patent. Furthermore, Airgas has amended its ANDA to include a Section viii Statement with regard to the '6,794 patent and will not infringe the '6,794 patent for this additional reason.

**Fifth Affirmative Defense**  
**(Invalidity of U.S. Patent No. 8,776,794)**

Upon information and belief, the claims of the '6,794 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

**Sixth Affirmative Defense**  
**(Noninfringement of U.S. Patent No. 8,776,795)**

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Airgas's ANDA No. 203144 will directly or indirectly infringe,

either literally or under the doctrine of equivalents, any valid claim of the '795 patent.

Furthermore, Airgas has amended its ANDA to include a Section viii Statement with regard to the '795 patent and will not infringe the '795 patent for this additional reason.

**Seventh Affirmative Defense**  
**(Invalidity of U.S. Patent No. 8,776,795)**

Upon information and belief, the claims of the '795 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

**Eighth Affirmative Defense**  
**(Noninfringement of U.S. Patent No. 9,279,794)**

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Airgas's ANDA No. 203144 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '9,794 patent. Furthermore, Airgas has amended its ANDA to include a Section viii Statement with regard to the '9,794 patent and will not infringe the '9,794 patent for this additional reason.

**Ninth Affirmative Defense**  
**(Invalidity of U.S. Patent No. 9,279,794)**

Upon information and belief, the claims of the '9,794 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

**Tenth Affirmative Defense**  
**(Noninfringement of U.S. Patent No. 10,773,046)**

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the

accused products infringe or will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '046 patent.

**Eleventh Affirmative Defense**  
**(Invalidity of U.S. Patent No. 10,773,046)**

Upon information and belief, the claims of the '046 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

**Twelfth Affirmative Defense**  
**(Noninfringement of U.S. Patent No. 9,919,118)**

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the accused products will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '118 patent.

**Thirteenth Affirmative Defense**  
**(Invalidity of U.S. Patent No. 9,919,118)**

Upon information and belief, the claims of the '118 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

**Fourteenth Affirmative Defense**  
**(No Injunctive Relief)**

Plaintiffs may not seek injunctive relief under 35 U.S.C. §§ 274(e)(4)(B) and/or 283 against Airgas because Plaintiffs' alleged damages are not irreparable and Plaintiffs have an adequate remedy at law.

**Fifteenth Affirmative Defense**  
**(No Costs)**

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

**Sixteenth Affirmative Defense**  
**(No Exceptional Case)**

Airgas's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

**Seventeenth Affirmative Defense**  
**(Equitable Defenses)**

Airgas reserves the right to amend its answer to include equitable defenses, such as inequitable conduct, unclean hands, laches, estoppel and/or patent misuse, if information obtained in discovery provides support for such a defense.

**Eighteenth Affirmative Defense**  
**(Additional Defenses)**

Any additional legal or equitable defenses or counterclaims that discovery may reveal, including but not limited to, defenses of unenforceability, as well as any defenses raised by another defendant in any action involving the '741, '6,794, '795, '9,794, '046 or '118 patents. Airgas reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

**RESERVATION OF DEFENSES**

Airgas hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

WHEREFORE, Airgas hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

## **COUNTERCLAIMS**

For their counterclaims against Counterclaim-Defendants Mallinckrodt Pharmaceuticals Ireland Limited (“Mallinckrodt Ireland”) and Mallinckrodt Hospital Products IP Unlimited Company (“Mallinckrodt Hospital”) and INO Therapeutics LLC (“INO Therapeutics”), (collectively “Mallinckrodt” or “Counterclaim-Defendants”), Counterclaim-Plaintiffs Airgas Therapeutics LLC (“Airgas Therapeutics”) and Airgas USA LLC (“Airgas USA”) (collectively “Airgas” or “Counterclaim-Plaintiffs”), state as follows:

## **BACKGROUND AND PARTIES**

1. This is an action for declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 8,795,741 (“the ’741 patent”), 8,776,794 (“the ’6,794 patent”), 8,776,795 (“the ’795 patent”), 9,279,794 (“the ’9,794 patent”), 10,773,046 (“the ’046 patent”), and 9,919,118 (“the ’118 patent”) (collectively, the “Patents-in-Suit”), pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the patent laws of the United States, 35 U.S.C. § 1, et seq.; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”) (21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5)).

2. Counterclaim-Plaintiff Airgas Therapeutics is the owner of Abbreviated New Drug Application (“ANDA”) No. 203144 and is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 6141 Easton Rd. Building 3, Plumsteadville, PA 18949.

3. Counterclaim-Plaintiff Airgas USA is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 259 N. Radnor Chester Road, Suite 100, Radnor, PA 19087.

4. Counterclaim-Defendant Mallinckrodt Ireland is a plaintiff in the underlying action and has averred that it is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland.

5. Counterclaim-Defendant Mallinckrodt Hospital is a plaintiff in the underlying action and has averred that it is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland.

6. Counterclaim Defendant INO Therapeutics is a plaintiff in the underlying action and has averred that it is a company organized and existing under the law of Delaware, with a principle place of business at 675 McDonnell Blvd., St. Louis, MO 63042.

7. Mallinckrodt Ireland has averred that it is a wholly-owned, indirect subsidiary of Mallinckrodt plc.

8. Mallinckrodt Ireland has averred that it is an assignee of the Orange Book Patents.

9. Mallinckrodt Hospital has averred that it is a wholly-owned, indirect subsidiary of Mallinckrodt plc.

10. Mallinckrodt Hospital has averred that it is the holder of New Drug Application (“NDA”) No. 020845 for INOmax®, 800 ppm.

11. INO Therapeutics has averred that it is a wholly owned indirect subsidiary of Mallinckrodt plc.

12. INO Therapeutics has averred that is commercializes the NDA Product.

### **JURISDICTION AND VENUE**

13. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

14. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

15. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges of this forum by bringing this civil action in this judicial district and because, upon information and belief, Counterclaim-Defendants conduct substantial business in, and have regular and systematic contact with, this judicial district.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Counterclaim-Defendants commenced the underlying action in this venue.

17. Because of Counterclaim-Defendants' Complaint against Airgas, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the Orange Book Patents.

### **FACTUAL BACKGROUND**

#### **A. FDA Approval of Brand Name Pharmaceuticals**

18. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

19. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

20. An NDA must include, among other things, the number of any patent that allegedly claims the “drug” or a “method of using [the] drug” for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1)-(c)(2); 21 C.F.R. § 314.53(b)(1),-(c)(2).

21. Upon approval of the NDA, the FDA publishes patent information for the approved drug in Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the “Orange Book.” *See* 21 C.F.R. § 314.53(e).

22. The FDA’s duties with respect to Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or “reference listed drug”), but instead relies on the NDA holder to properly list the patent.

### **B. FDA Approval of Brand Name Pharmaceuticals**

23. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

24. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application (“ANDA”).

25. Among other things, an ANDA must also contain a “certification” as to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in



connection with the reference listed drug. See 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

26. A “Paragraph IV” certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

27. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

28. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker’s ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

29. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, “including any substantive determination that there is no cause of action for patent infringement or invalidity,” the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

### **C. NDA No. 020845 and The Patents-In-Suit**

30. According to the Orange Book, Mallinckrodt Hospital is the holder of New Drug Application (“NDA”) No. 020845 under which the FDA granted approval for INOmax®, 800 ppm.

31. NDA holders are required to disclose to the FDA the patent number of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

32. The Orange Book lists the '741,'6,794, '795, and '9,794, (collectively, the "Orange Book Patents") in association with NDA No. 020845 for INOmax®, 800 ppm.

33. On information and belief, Mallinckrodt Hospital caused the Orange Book Patents to be listed in the Orange Book in connection with NDA No. 020845.

### **The Praxair Litigation**

34. Mallinckrodt previously asserted the '966, '284, '741, '163, '112, '6,794, '795, '209, '911,'802, and '9,794 patents in *Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distribution, Inc.*, 1:15-cv-00170 (D. Del.) ("the Praxair Litigation"), alleging infringement under 35 U.S.C. §§ 271(e)(2) and 271(a), (b) and/or (c).

35. The district court decision (D.E. 308) referred to the '966, '284, '741, '163, and '112 patents as the "HF patents."

36. The district court held that the asserted claims of the HF patents were invalid under 35 U.S.C. § 101. *See* D.E. 308, 309, 310.

37. The district court decision (D.E. 308) referred to the '6,794, '795, '209, '911, and '802 patents as the "DSIR patents."

38. The district court held that the asserted claims of the DSIR patents were not infringed. *See* D.E. 308, 309, 310.

39. The district court decision (D.E. 308) referred to the '9,794 patent as the "Sensor Drift Patent."

40. The district court held that the asserted claims of the Sensor Drift Patent were not infringed. *See* D.E. 308, 309, 310.

41. The district court found that each of the patent claims ultimately asserted by Mallinckrodt against Praxair was either invalid or not infringed. *See* D.E. 308, 309, 310.

42. The Federal Circuit upheld the district court's invalidity and non-infringement findings concerning the asserted claims. *See INO Therapeutics LLC v. Praxair Distribution Inc.*, 782 Fed. Appx. 1001 (Fed. Cir. 2019).

#### **The '741 Patent**

43. Upon information and belief, on or about August 5, 2014, the USPTO issued the '741 patent, entitled "Methods for treating patients who are candidates for inhaled nitric oxide treatment."

44. Counterclaim Defendant Mallinckrodt Ireland has averred that it is the assignee of the '741 patent and that a true and accurate copy of the '741 patent is attached as Exhibit 2 to the Complaint.

45. Counterclaim Defendants have averred that the '741 patent is listed in FDA's Orange Book for INOmax®.

#### **The '6,794 Patent**

46. Upon information and belief, on or about July 15, 2014, the USPTO issued the '6,794 patent, entitled "Nitric Oxide Delivery Device."

47. Counterclaim Defendant Mallinckrodt Ireland has averred that it is the assignee of the '6,794 patent and that a true and accurate copy of the '6,794 patent is attached as Exhibit 3 to the Complaint.

48. Counterclaim Defendants have averred that the '6,794 patent is listed in FDA's Orange Book for INOmax®.

**The '795 Patent**

49. Upon information and belief, on or about July 15, 2014, the USPTO issued the '795 patent, entitled "Gas delivery device and system."

50. Counterclaim Defendant Mallinckrodt Ireland has averred that it is the assignee of the '795 patent and that a true and accurate copy of the '795 patent is attached as Exhibit 4 to the Complaint.

51. Counterclaim Defendants have averred that the '795 patent is listed in FDA's Orange Book for INOmax®.

**The '9,794 Patent**

52. Upon information and belief, on or about March 8, 2016, the USPTO issued the '9,794 patent, entitled "Systems and methods for compensating long term sensitivity drift of electrochemical gas sensors exposed to nitric oxide."

53. Counterclaim Defendant Mallinckrodt Ireland has averred that it is the assignee of the '9,794 patent and that a true and accurate copy of the '9,794 patent is attached as Exhibit 5 to the Complaint.

54. Counterclaim Defendants have averred that the '9,794 patent is listed in FDA's Orange Book for INOmax®.

**The '046 Patent**

55. Upon information and belief, on or about September 15, 2020, the USPTO issued the '046 patent, entitled "Apparatus and method for monitoring nitric oxide delivery."

56. Counterclaim Defendant Mallinckrodt Ireland has averred that it is the assignee of the '046 patent and that a true and accurate copy of the '046 patent is attached as Exhibit 6 to the Complaint.

**The '118 Patent**

57. Upon information and belief, on or about August 9, 2016, the USPTO issued the '118 patent, entitled “Systems and methods for compensating long term sensitivity drift of electrochemical gas sensors exposed to nitric oxide.”

58. Counterclaim Defendant Mallinckrodt Ireland has averred that it is the assignee of the '118 patent and that a true and accurate copy of the '118 patent is attached as Exhibit 7 to Complaint.

**D. Airgas's ANDA**

59. Airgas Therapeutics filed Abbreviated New Drug Application (“ANDA”) No. 203144 (Airgas's ANDA) to the FDA, seeking approval for inhalable nitric oxide 800 ppm (Airgas's ANDA Product) prior to expiration of the Orange Book Patents.

60. Airgas's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”) that, in Airgas Therapeutics' opinion and to the best of its knowledge, Airgas's ANDA Product would not infringe any valid claim of the '570 patent, the '741 patent, the '904 patent, the '209 patent, the '210 patent, the '6,794 patent , the '795 patent , the '911 patent , the '9,794 patent , the '802 patent, the '993 patent , the '966 patent , the '284 patent, the '163 patent , and the '112 patent, which are all the patents listed in the Orange Book in association with NDA No. 020845 for INOmax®, 800 ppm.

61. Pursuant to 21 U.S.C. § 355(j)(2)(B), Airgas Therapeutics sent, or caused to be sent, to Counterclaim-Defendants a letter dated November 17, 2022 (“Airgas Therapeutics’

Notice Letter”), detailing the legal and factual bases for its Paragraph IV certification that Airgas’s ANDA would not infringe any valid claim of the Orange Book Patents (the “detailed statement”), detailing multiple bases for Airgas Therapeutics’ certification as to each claim of the Orange Book Patents, and including an Offer of Confidential Access in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III) to allow Counterclaim-Defendants to inspect relevant portions of Airgas’s ANDA.

62. On December 9, 2022, Airgas Therapeutics amended its ANDA to include a statement under 21 U.S.C. § 355(j)(2)(A)(viii) and 21 C.F.R. § 314.94(a)(12)(iii)(A), (“Section viii Statement”) with respect to the ’904 patent, ’210 patent, ’6,794 patent, ’795 patent, ’911 patent, ’9,794 patent, ’993 patent, and ’570 patent.

63. Counterclaim Defendants refused the terms and conditions of the Offer of Confidential Access.

64. Counterclaim Defendants initiated the present litigation by filing a complaint against Airgas Therapeutics, Airgas USA, and Air Liquide S.A. on December 30, 2022, alleging that “Defendants’ submission of Defendants’ ANDA to FDA, including their Paragraph IV certification, constitutes an act of infringement under 35 U.S.C. § 271(e)(2)(A). In the event that Defendants commercially manufacture, use, offer for sale, sell, and/or import into the United States the Defendants’ Proposed ANDA Product or induces or contributes to such conduct, said actions would constitute infringement under 35 U.S.C. § 271(a), (b), and/or (c).”

65. Counterclaim-Defendants did not review Airgas’s ANDA in the instant action prior to filing suit.

66. Counterclaim-Defendants did not perform a prefiling infringement investigation of Airgas's ANDA product.

67. As a consequence of the foregoing, there is an actual and justiciable controversy between Airgas and Counterclaim-Defendants as to whether Airgas's ANDA infringes the Patents-in-Suit, or whether the manufacture, use, sale, offer for sale, and/or importation of the product that is the subject of Airgas's ANDA would infringe the Patents-in-Suit.

**COUNT I**  
**(Declaratory Judgment of Invalidity of U.S. Patent No. 8,795,741)**

68. Airgas restates and realleges each of the foregoing paragraphs 1-67 of the Counterclaims as if fully set forth herein.

69. Counterclaim-Defendants allege that Airgas Therapeutics' filing of ANDA No. 203144 infringes the '741 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Product would infringe the '741 patent.

70. As evidenced by Counterclaim Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim Defendants regarding the validity of the claims of the '741 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

71. In accordance with 21 U.S.C. § 355(j)(2)(B), Airgas Therapeutics' Notice Letter included a detailed statement of factual and legal bases for why the claims of the '741 patent are invalid. Airgas Therapeutics incorporates by reference Airgas Therapeutics' Notice Letter.

72. Based at least upon the facts and the reasons set forth in the detailed statement accompanying Airgas Therapeutics' Notice Letter, the claims of the '741 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

73. Airgas is entitled to a judicial determination that the claims of the '741 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

**COUNT II**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,795,741)**

74. Airgas restates and realleges each of the foregoing paragraphs 1-73 of the Counterclaims as if fully set forth herein.

75. Counterclaim-Defendants allege that Airgas Therapeutics' filing of ANDA No. 203144 infringes the '741 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Product would infringe the '741 patent.

76. As evidenced by Counterclaim-Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim-Defendants regarding the infringement of the claims of the '741 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

77. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by



Airgas of its proposed ANDA Product pursuant to ANDA No. 203144 will not infringe, directly or indirectly, any valid claim of the '741 patent under any provision of 35 U.S.C. § 271.

78. The proposed ANDA Product, which may be marketed upon approval of ANDA No. 203144, would not infringe any valid claim of the '741 patent, either literally or under the doctrine of equivalents.

79. Airgas is entitled to a judicial determination that the proposed ANDA Product which is the subject of ANDA No. 203144 has not infringed, does not infringe, and would not, if marketed, infringe any valid claim of the '741 patent.

**COUNT III**  
**(Declaratory Judgment of Invalidity of U.S. Patent No. 8,776,794)**

80. Airgas restates and realleges each of the foregoing paragraphs 1-79 of the Counterclaims as if fully set forth herein.

81. Counterclaim-Defendants allege that Airgas Therapeutics' filing of ANDA No. 203144 infringes the '6,794 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Product would infringe the '6,794 patent.

82. As evidenced by Counterclaim Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim Defendants regarding the validity of the claims of the '6,794 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

83. In accordance with 21 U.S.C. § 355(j)(2)(B), Airgas Therapeutics' Notice Letter included a detailed statement of factual and legal bases for why the claims of the '6,794 patent are invalid. Airgas Therapeutics incorporates by reference Airgas Therapeutics' Notice Letter.

84. Based at least upon the facts and the reasons set forth in the detailed statement accompanying Airgas Therapeutics' Notice Letter, the claims of the '6,794 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

85. Airgas is entitled to a judicial determination that the claims of the '6,794 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

**COUNT IV**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,776,794)**

86. Airgas restates and realleges each of the foregoing paragraphs 1-85 of the Counterclaims as if fully set forth herein.

87. Counterclaim-Defendants allege that Airgas Therapeutics' filing of ANDA No. 203144 infringes the '6,794 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Product would infringe the '6,794 patent.

88. As evidenced by Counterclaim-Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim-Defendants regarding the infringement of the claims of the '6,794 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

89. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by Airgas of its proposed ANDA Product pursuant to ANDA No. 203144 will not infringe, directly or indirectly, any valid claim of the '6,794 patent under any provision of 35 U.S.C. § 271. Furthermore, Airgas has amended its ANDA to include a Section viii Statement with regard to the '6,794 patent and will not infringe the '6,794 patent for this additional reason.

90. The proposed ANDA Product, which may be marketed upon approval of ANDA No. 203144, would not infringe any valid claim of the '6,794 patent, either literally or under the doctrine of equivalents.

91. Airgas is entitled to a judicial determination that the proposed ANDA Product which is the subject of ANDA No. 203144 has not infringed, does not infringe, and would not, if marketed, infringe any valid claim of the '6,794 patent.

**COUNT V**  
**(Declaratory Judgment of Invalidity of U.S. Patent No. 8,776,795)**

92. Airgas restates and realleges each of the foregoing paragraphs 1-91 of the Counterclaims as if fully set forth herein.

93. Counterclaim-Defendants allege that Airgas Therapeutics' filing of ANDA No. 203144 infringes the '795 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Product would infringe the '795 patent.

94. As evidenced by Counterclaim Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim Defendants regarding the validity of the claims of the '795 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

95. In accordance with 21 U.S.C. § 355(j)(2)(B), Airgas Therapeutics' Notice Letter included a detailed statement of factual and legal bases for why the claims of the '795 patent are invalid. Airgas Therapeutics incorporates by reference Airgas Therapeutics' Notice Letter.

96. Based at least upon the facts and the reasons set forth in the detailed statement accompanying Airgas Therapeutics' Notice Letter, the claims of the '795 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

97. Airgas is entitled to a judicial determination that the claims of the '795 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

**COUNT VI**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,776,795)**

98. Airgas restates and realleges each of the foregoing paragraphs 1-97 of the Counterclaims as if fully set forth herein.

99. Counterclaim-Defendants allege that Airgas Therapeutics' filing of ANDA No. 203144 infringes the '795 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Product would infringe the '795 patent.

100. As evidenced by Counterclaim-Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim-Defendants regarding the infringement of the claims of the '795 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

101. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by Airgas of its proposed ANDA Product pursuant to ANDA No. 203144 will not infringe, directly or indirectly, any valid claim of the '795 patent under any provision of 35 U.S.C. § 271. Furthermore, Airgas has amended its ANDA to include a Section viii Statement with regard to the '795 patent and will not infringe the '795 patent for this additional reason.

102. The proposed ANDA Product, which may be marketed upon approval of ANDA No. 203144, would not infringe any valid claim of the '795 patent, either literally or under the doctrine of equivalents.

103. Airgas is entitled to a judicial determination that the proposed ANDA Product which is the subject of ANDA No. 203144 has not infringed, does not infringe, and would not, if marketed, infringe any valid claim of the '795 patent.

**COUNT VII**  
**(Declaratory Judgment of Invalidity of U.S. Patent No. 9,279,794)**

104. Airgas restates and realleges each of the foregoing paragraphs 1-103 of the Counterclaims as if fully set forth herein.

105. Counterclaim-Defendants allege that Airgas Therapeutics' filing of ANDA No. 203144 infringes the '9,794 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Product would infringe the '9,794 patent.

106. As evidenced by Counterclaim Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim Defendants regarding the validity of the claims of the '9,794 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

107. In accordance with 21 U.S.C. § 355(j)(2)(B), Airgas Therapeutics' Notice Letter included a detailed statement of factual and legal bases for why the claims of the '9,794 patent are invalid. Airgas Therapeutics incorporates by reference Airgas Therapeutics' Notice Letter.

108. Based at least upon the facts and the reasons set forth in the detailed statement accompanying Airgas Therapeutics' Notice Letter, the claims of the '9,794 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

109. Airgas is entitled to a judicial determination that the claims of the '9,794 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

**COUNT VIII**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,279,794)**

110. Airgas restates and realleges each of the foregoing paragraphs 1-109 of the Counterclaims as if fully set forth herein.

111. Counterclaim-Defendants allege that Airgas Therapeutics' filing of ANDA No. 203144 infringes the '9,794 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Product would infringe the '9,794 patent.

112. As evidenced by Counterclaim-Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim-Defendants regarding the infringement of the claims of the '9,794 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

113. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by Airgas of its proposed ANDA Product pursuant to ANDA No. 203144 will not infringe, directly or indirectly, any valid claim of the '9,794 patent under any provision of 35 U.S.C. § 271. Furthermore, Airgas has amended its ANDA to include a Section viii Statement with regard to the '9,794 patent and will not infringe the '9,794 patent for this additional reason.

114. The proposed ANDA Product, which may be marketed upon approval of ANDA No. 203144, would not infringe any valid claim of the '9,794 patent, either literally or under the doctrine of equivalents.

115. Airgas is entitled to a judicial determination that the proposed ANDA Product which is the subject of ANDA No. 203144 has not infringed, does not infringe, and would not, if marketed, infringe any valid claim of the '9,794 patent.

**COUNT IX**  
**(Declaratory Judgment of Invalidity of U.S. Patent No. 10,773,046)**

116. Airgas restates and realleges each of the foregoing paragraphs 1-115 of the Counterclaims as if fully set forth herein.

117. Counterclaim-Defendants allege that Defendants' manufacture, use, offer for sale, sale or importation of the accused product would infringe the '046 patent.

118. As evidenced by Counterclaim Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim Defendants regarding the validity of the claims of the '046 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

119. The claims of the '046 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.



120. Airgas is entitled to a judicial determination that the claims of the '046 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

**COUNT X**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,773,046)**

121. Airgas restates and realleges each of the foregoing paragraphs 1-120 of the Counterclaims as if fully set forth herein.

122. Counterclaim-Defendants allege that Defendants' manufacture, use, offer for sale, sale or importation of the proposed accused product would infringe the '046 patent.

123. As evidenced by Counterclaim-Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim-Defendants regarding the infringement of the claims of the '046 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

124. The manufacture, use, sale, offer for sale, and/or importation by Airgas of its accused product will not infringe, directly or indirectly, any valid claim of the '046 patent under any provision of 35 U.S.C. § 271.

125. Airgas is entitled to a judicial determination that the accused product has not infringed, does not infringe, and would not, if marketed, infringe any valid claim of the '046 patent.

**COUNT XI**  
**(Declaratory Judgment of Invalidity of U.S. Patent No. 9,919,118)**

126. Airgas restates and realleges each of the foregoing paragraphs 1-125 of the Counterclaims as if fully set forth herein.

127. Counterclaim-Defendants allege that Airgas Therapeutics' accused product infringes the '118 patent and that the manufacture, use, offer for sale, sale or importation of the proposed accused product would infringe the '118 patent.

128. As evidenced by Counterclaim Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim Defendants regarding the validity of the claims of the '118 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

129. The claims of the '118 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

130. Airgas is entitled to a judicial determination that the claims of the '118 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103 and/or 112.

**COUNT XII**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,919,118)**

131. Airgas restates and realleges each of the foregoing paragraphs 1-130 of the Counterclaims as if fully set forth herein.

132. Counterclaim-Defendants allege that Airgas Therapeutics' accused product infringes the '118 patent and that the manufacture, use, offer for sale, sale or importation of the proposed accused product would infringe the '118 patent.

133. As evidenced by Counterclaim-Defendants' Complaint and Airgas's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Airgas and Counterclaim-Defendants regarding the infringement of the claims of the '118 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

134. The manufacture, use, sale, offer for sale, and/or importation by Airgas of its accused product pursuant to will not infringe, directly or indirectly, any valid claim of the '118 patent under any provision of 35 U.S.C. § 271.

135. The accused product would not infringe any valid claim of the '118 patent, either literally or under the doctrine of equivalents.

136. Airgas is entitled to a judicial determination that the accused product has not infringed, does not infringe, and would not, if marketed, infringe any valid claim of the '118 patent.

#### **PRAYER FOR RELIEF**

WHEREFORE, Counterclaim-Plaintiffs respectfully request that this Court enter a judgment in their favor and against Counterclaim-Defendants as follows:

- a. Declaring that the filing of Airgas's ANDA did not infringe any valid and enforceable claim of the Patents-in-Suit;

- b. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Airgas's ANDA Product described in Airgas's ANDA has not infringed, does not infringe, and would not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit either literally or under the doctrine of equivalents;
- c. Declaring that the claims of the '741 patent are invalid;
- d. Declaring that the claims of the '6,794 patent are invalid;
- e. Declaring that the claims of the '6,795 patent are invalid;
- f. Declaring that the claims of the '9,794 patent are invalid;
- g. Declaring that the claims of the '046 patent are invalid;
- h. Declaring that the claims of the '118 patent are invalid;
- i. Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of Airgas;
- j. Denying Plaintiffs/Counterclaim Defendants any of the relief requested in the Complaint;
- k. Declaring this case exceptional in favor of Airgas pursuant to 35 U.S.C. § 285;
- l. Awarding costs and attorneys' fees to Airgas; and,
- m. Awarding Airgas such other and further relief the Court may deem just and proper.

Dated: February 26, 2024

By: /s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)

Megan C. Haney (#5016)

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